

Remarks

Claim 92 is pending in this application. No claim amendments are made in this paper. No new matter has been introduced.

Applicants appreciate the Examiner's withdrawal of the obviousness-type double patenting rejections over U.S. application no. 11/091,518 and U.S. patent no. 6,911,479 are withdrawn. However, the rejection of claim 92 as allegedly obvious over EP 0639374 A2 to Rudolph *et al.* ("the '374 publication") is maintained in the Office Action. Applicants respectfully submit that the rejection should be also withdrawn for at least the following reasons.

A. The Rejection Under 35 U.S.C. §103

On pages 3-8 of the Office Action, claim 92 is rejected as allegedly obvious over EP 0639374 A2 to Rudolph *et al.* ("the '374 publication"). The Office Action acknowledges that the '374 publication "does not explicitly teach a method of treating anxiety with the (-)-enantiomer of O-desmethylvenlafaxine," but alleges that claim 92 would have been obvious because "the skilled artisan would have expected optical isomers to be separable and isomers so separated to exhibit physiological effects at varying levels." (Office Action, page 5). The Office Action also alleges that "[i]t is well-settled [in] patent law that optical isomers would have been expected to possess different therapeutic activities." (*Id.*).

As previously submitted, Applicants point out that the allegations set forth in the previous (and the current) Office Action does indeed amount to the proposition that no claims to optical isomers are *prima facie* non-obvious over prior disclosure of a racemic mixture, which is flatly contrary to the legal principles concerning the non-obviousness of optical isomers. The Examiner appears to suggest that the allegations set forth in the Office Action do not amount to such a proposition. Rather, according to the Examiner, "an optical isomer is *prima facie* obvious over the racemic mixture provided there is not a different[ce] in kind between the isomers" (Office Action, page 6). The Examiner goes on to state that "[a] different[ce] in kind is considered unexpected results." (*Id.*).

What is alleged in the Office Action is then a proposition that an optical isomer is *per se prima facie* obvious unless unexpected results are provided. However, this proposition confuses and mixes up two different legal principles, *i.e.*, *prima facie* case of obviousness and rebuttal based on unexpected results. It is well-settled that unexpected results are only required to rebut a properly established *prima facie* case of obviousness. (See, *e.g.*, *In re Wiechert*, 370 F.2d 927 (C.C.P.A. 1967)). In other words, no unexpected

results are required to evidence the patentability of a claim unless a *prima facie* case of obviousness is properly established by the Patent Office. In this regard, Applicants respectfully submit that no *prima facie* case of obviousness is properly established in this application.

This is because the obviousness rejection is provided in the Office Action based on allegations without any scientific or factual evidence that supports such allegations. Only rationale provided to support the purported *prima facie* case of obviousness is an unfounded assertion that reasonable expectation of success would have allegedly existed since “it is expected that one or another optical isomer will exhibit a greater or lesser physiological effect, and thus better pharmaceutical properties.” (Office Action, page 7). However, not only is that statement scientifically incorrect, the statement is directly contrary to the legal principles. *See, e.g., Sanofi-Synthelabo v. Apotex, Inc.*, 492 F.Supp.2d 353 (S.D.N.Y. 2007). Stressing the importance of determining whether a skilled artisan would have possessed a reasonable expectation of success, the *Sanofi* Court concluded that the claimed enantiomer was non-obvious because, *inter alia*, “the prior art did not enable a person of ordinary skill in the art to predict with a reasonable expectation of success whether one enantiomer of [the claimed compound] would have better pharmaceutical properties than the racemate itself.” *Id.* at 390 (emphasis added). *See also Forest Labs., Inc. v. Ivax Pharmaceuticals, Inc.* 438 F.Supp.2d 479, 493 (D. Del. 2006) (“unpredictable nature of the separation of racemic compounds” meant that “a person skilled in the art seeking such a resolution would not have a reasonable expectation of success without undue experimentation”) (emphasis added), *aff’d.*, *Forest Labs., Inc. v. Ivax Pharmaceuticals, Inc.*, 501 F.3d 1263, 1269 (Fed. Cir. 2007) (“[T]he district court’s key factual findings underlying its conclusions on obviousness are not clearly erroneous.”).

Therefore, relevant legal principles clearly indicate that a “reasonable expectation” is indeed required regarding “whether one enantiomer ... would have better pharmaceutical properties than the racemate itself.” Thus, the unfounded allegation in the Office Action that “it is expected that one or another optical isomer will exhibit a greater or lesser physiological effect, and thus better pharmaceutical properties” is simply legally insufficient form a basis for a *prima facie* case of obviousness.¹

Further in this regard, Applicants respectfully point out that the ‘374 publication falls far short of providing any expectation of success in connection with Applicants’ present claim 92. For example, although anxiety is disclosed in the ‘374

¹ This allegation is also scientifically unsound because it completely ignores other factors such as separation of enantiomers and adverse effects profiles.

publication as one of various disorders that may allegedly be treated by racemic ODMV, there is no teaching or suggestion in the '374 publication that would have provided to those skilled in the art with any expectation of successfully treating the specific disorder anxiety using the specific ODMV enantiomer as recited in Applicants' present claim 92.

In addition, there is no disclosure or guidance in the '374 publication that would enable those skilled in the art to "predict with a reasonable expectation of success whether [the claimed (-)-isomer] would have better pharmaceutical properties than the racemate itself." (*Sanofi-Synthelabo*, 492 F.Supp.2d at 390). Consequently, Applicants respectfully submit that no prima facie case of obviousness is established by the '374 publication, and thus, respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

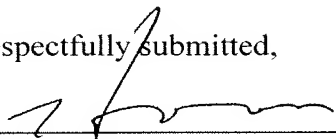
B. Conclusion

For at least the foregoing reasons, Applicants respectfully submit that claim 92 is allowable, and thus, respectfully request the withdrawal of its rejections.

No fee is believed to be due for the submission of this paper. If any fees are required for the submission of this paper, or to avoid abandonment of this application, the Director is authorized to charge the required fees to Jones Day Deposit Account No. 50-3013.

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Respectfully submitted,


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